1644

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

PATENTS

#6 9/7/01 Gray

In re application of

Marian Elizabeth LUDGATE

Serial No. 09/509,687

Filed April 19, 2000

BIOASSAY FOR THYROID STIMULATING ANTIBODIES

GROUP 1644

Examiner P. Nolan

PETITION FOR EXTENSION OF TIME

Commissioner for Patents

Washington, D.C. 20231

Sir:

The undersigned hereby petitions for an extension of time to respond to the Official Action of July 2, 2001 for one month to September 2, 2001.

Please charge the extension fee of $55 to Deposit Account No. 25-0120. If this fee is insufficient, the Patent Office is hereby authorized to charge any additional extension fee to Deposit Account No. 25-0120. A duplicate copy of this sheet is enclosed.

A responsive paper is filed herewith.

Respectfully submitted,

YOUNG & THOMPSON

By _____

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September 4, 2001

#7 9/7/01 TBray

PATENTS

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RESPONSE TO LACK OF UNITY DETERMINATION

Commissioner for Patents

Washington, D.C. 20231

Sir:

Responsive to the lack of unity determination set forth in the Official Action of July 2, 2001, applicant hereby provisionally elects Group IV, claims 36-42, with traverse. The grounds for traverse are as follows:

Pursuant to 37 CFR §1.143, applicant respectfully requests reconsideration of the lack of unity determination and withdrawal of the same, on the basis that the present claims 1-43 in fact do not lack unity of invention as contemplated in 37 CFR §1.499. In particular, applicant respectfully disagrees with the analysis set forth in the Official Action that claims 1-43 do not share a "special technical feature" in view of the combined teachings of LUDGATE and HIMMLER et al.

Initially, we observe that item 4 of the lack of unity determination is confusing, in that only Groups I-III are referenced, whereas the lack of unity determination is formulated

in terms of Groups I-V. As to the following discussion at Item 4, the proposed combination of LUDGATE and HIMMLER is premised on the contention that a person of ordinary skill in the art, seeking to simplify the method of LUDGATE, would (a) consider the disclosure of HIMMLER et al. in the first instance, and (b) have a reasonable expectation of achieving the present invention upon combining those disclosures in the manner proposed in the Official Action. However, applicant respectfully submits that neither of those propositions finds adequate factual basis in the present record.

At the date the invention was made, the inventor of the presently-claimed subject matter was beginning from the point she had arrived at, which is described in LUDGATE. The question she was faced with was how to overcome the numerous disadvantages of this assay, not least the length of time it takes to perform, especially in view of having to detect the generated cAMP by radio immuno-assay, and also the fact that the method requires tissue culture facilities to be available.

Absent application of inventive skill, one trying to find an improvement for the existing assay, would logically first look towards assays for related substrates i.e., substrates related to TSH-R auto-antibodies or TSH. An appropriate place to start looking would be amongst G-protein coupled receptors (GPCR). However, there are currently more than 1,000 GPCR, of which more than 300 are of human origin. GPCR couple to a range

of signaling pathways, including adenylate cyclase (both stimulatory and inhibitory), inositol phosphate, and calcium signaling and ion channels. The applicant has, in fact, searched in computer databases (such as BIDS) for papers relating to GPCR that are also concerned with adenylate cyclase or cAMP. This search gives rise to many hits regarding the biology of the receptors, but nothing relevant to novel detection methods; HIMMLER et al. is not included amongst these hits. Furthermore BIDS searches using cAMP detection, cAMP assay, cAMP responsive reporter, cAMP or signal transduction as key words also do not give rise to any useful results. In particular, amongst these searches, either HIMMLER et al. do not appear or there are so many hits that it is not feasible to review them all. It is therefore difficult to see how the solution finally arrived at ~~(of using the particular construct as defined in the claims)~~ would have been obvious in the light of such prior art.

Even were HIMMLER et al. to have appeared in any of these searches or even were the inventors otherwise aware of the HIMMLER et al. paper, it is difficult to see how they would have been led to believe that its disclosure provided the solution to the problem of a TSH-related assay. It is highly significant that the HIMMLER et al. paper focuses on certain dopamine receptors with a view to testing the response of putative dopamine receptor drugs. The dopamine receptor family comprises five subtypes, several of which have further subvariants.

Although D_1 and D_5 couple to adenylate cyclase (stimulatory), the other three sub-types inhibit adenylate cyclase or are coupled to ion channels. Hence, the dopamine receptor family is by no means an obvious one with which to draw an analogy for the TSH receptor. HIMMLER et al. itself points out (page 91) that other dopamine systems based on CAT do not lend themselves to such an assay. Thus, given that a system based on the same receptor type cannot be assumed to work in a particular assay, there would plainly have been no reasonable expectation that a similar system would work on a completely different kind of receptor.

From the above discussion, therefore, it is believed to be apparent that the two references relied upon in the Official Action of July 2, 2001, in fact do not support a conclusion that the pending claims 1-43 lack a "special technical feature" within the meaning of PCT Rule 13.2. Instead, all of pending claims 1-43 share the common technical feature of the clone of the elected Group IV, which feature is indeed a "special technical feature" for the reasons discussed above.

In view of the present response, therefore, it is respectfully requested that the lack of unity determination be

withdrawn, and that all of pending claims 1-43 be examined on the merits of the present application.

Respectfully submitted,

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September 4, 2001